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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/701,278	08/22/1996	DAVID J. ANDERSON	A-63770-1/RF	5313
7590 04/08/2004				
FLEHR HOHBACH TEST ALBRITTON & HERBERT FOUR EMBARCADERO CENTER SUITE 3400 SAN FRANCISCO, CA 94111				
EXAMINER HAYES, ROBERT CLINTON				
ART UNIT		PAPER NUMBER		
1647				

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/701,278	ANDERSON ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 10/24/03 has been entered.
2. Applicant's arguments filed 10/24/03 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-2 & 4-7 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility, for the reasons made of record in Paper Nos. 26 (mailed 5/3/00), 29 (mailed 1/16/01), 33 (mailed 7/24/01), 36 (mailed 12/17/01), 38 (mailed 7/23/02) and 43 (mailed 6/19/03), and as follows.

Applicants argue on pages 5-7 of the response that the passage related to DRG11 being a general marker "similar to that of SCG10... or Isl-1" "has been taken out of context". In contrast to Applicants' assertions, and as previously made of record, many genes are putatively "characterized by [their] natural expression in sensory neurons and dorsal horn neurons [i.e., sensory neuronal cell bodies] and non-expression in non-neuronal cells, sympathetic neurons and ventricular neurons of the spinal cord", such as the examples of "SCG10... or Isl-1" described

within the instant specification. Therefore, the issue is simple. No “specific” utility is described within the instant specification for the DRG11 nucleic acid of SEQ ID NO: 1, especially as it relates for any variants thereof (i.e., as it relates to 90% and 95% sequence identities) which themselves have no known nor described “specific” function, because research tools by themselves do not define a “specific utility”. See MPEP 2107(I). Moreover, gene expression within a population of cells, by itself, is a general process; thereby, not “specifically” defining what DRG11 does, by definition, as previously made of record. Thus, Applicants’ arguments remain not persuasive for the reasons made of record; consistent with that held by the courts in *Vas-Cath Inc. v. Mahurkar*, and *Brenner v. Manson* previously made of record.

Likewise, because no function can be associated specifically with the encoded rat DRG11 gene product of the instant invention which, thereby, distinguishes it from any general sensory neuronal marker, and because no disease state is known in the art nor adequately described within the instant specification that is caused by dysfunctional DRG11 expression, no “substantial” utility further exists for the reasons made of record. Thus, Applicants’ arguments concerning substantial utility are also not persuasive for the reasons made of record. See MPEP 2107, 2107.1(I) & 2107.2(IIA).

5. Claims 1-2 & 4-7 stand also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons made of record in Paper NOs: 26, 29, 33, 36, 38 & 43.

6. Claims 1 & 5-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No proper antecedent basis nor conception in context with that described within the specification at the time of filing the instant application exists for mix and matching different % identities for different domains within an encoded region of a isolated cDNA molecule; thereby, constituting new matter.

7. Claims 1 & 5-7 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No. 26, 29, 33, 36, 38 & 43, and as follows.

Applicants argue on pages 8-12 of the response that "the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, (e.g., structure or other physical and/or chemical properties), by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus." The Examiner agrees. However, the issue remains that

the specification fails to describe “a representative number of species by actual reduction to practice”, and that neither the instant specification nor claims identify a single distinguishable functional characteristic that coupled with structural characteristics, or a “disclosed correlation between function and structure”, teach one of skill in the art “how to use” the instant invention. As previously made of record, the specification fails to define those critical nucleotide residues that define “expression in sensory neurons...”, in any species, including rat. Moreover, neither the claims nor specification disclose how one of ordinary skill in the art could use an assayable function for the claimed DRG11 variants to distinguish when one has successfully made and used the claimed “genus” (i.e., as it relates to non-rat DRG11 polynucleotides), or claimed subgenus (e.g., as it relates to rat allelic variants thereof, which the current claims further are not limited towards). In contrast to Applicants’ assertions, the one disclosed rat sequence of SEQ ID NO: 1 does not reasonably constitute a “genus”, or subgenus; consistent with that held by the courts in *Fiers v. Revel*, *Fiddes v. Baird* and *University of California v. Eli Lilly* previously made of record versus Applicants’ arguments. Thus, Applicants’ arguments remain not persuasive for the reasons extensively made of record. See MPEP 2163.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1647

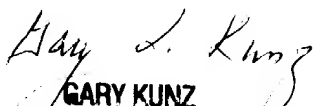
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887. The fax phone number for this Group is (703) 872-9306.



Robert C. Hayes, Ph.D.
April 6, 2004



GARY KUNZ
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